

REMARKS

The Applicants thank the Examiner for her thorough and thoughtful examination of the present application. Claims 1-18 and 31-45 were pending. With the present Amendment, the Applicants amend Claim 1; therefore, Claims 1-18 and 31-45 remain pending for consideration.

Claim Rejections Under 35 U.S.C. § 102

Claims 1-18 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,197,049 to Shaolian, et al. Applicants respectfully traverse the rejection, as Shaolian fails to teach all of the claim language.

Claims 1-17

Claim 1 has been amended to recite, “An endolumenal prosthesis having a luminal surface and an abluminal surface, comprising: a tubular wire support . . . and a tubular ePTFE sheath on the wire support, the tubular sheath having a sheath proximal end region and a sheath distal end region, wherein the sheath is configured to inhibit sufficient cellular ingrowth through the wall of the sheath to permit the formation of a viable neointimal layer on the luminal surface of the sheath at the sheath proximal and distal end regions.”

In contrast, Shaolian merely explains (emphasis added), “[I]n a central zone 57 of the prosthesis 42, the polymeric sleeve 44 may either be nonporous, or provided with pores of relatively lower porosity.” However, nowhere does Shaolian describe or suggest an ePTFE sheath configured to inhibit sufficient cellular ingrowth through its wall to permit the formation of a viable neointimal layer on the luminal surface of the sheath at the sheath proximal and distal end regions.”

The M.P.E.P. explains that in order to anticipate a claim under 35 U.S.C. § 102, “the reference must teach every element of the claim. ‘A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.’” M.P.E.P. § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)) (emphasis added).

Because Shaolian does not teach or suggest all of the claim language, Shaolian cannot anticipate Claim 1. Therefore, for at least these reasons, Claim 1 distinguishes over the applied art. Claims 2-17 depend from Claim 1, and therefore distinguish over the applied art for at least

the same reasons. In addition, Claims 2-17 distinguish over the applied art for the unique combinations of features recited in those claims.

For example, Shaolian does not teach an ePTFE sheath having a wall thickness of no greater than about 0.2 mm (as required in Claim 2), a density of at least about 0.5 g/ml, 0.75 g/ml, or within the range of from about 1.1 to about 1.5 g/ml (as required in Claims 5-7, respectively), an average distance between ePTFE nodes within a range of from about 6 microns to about 80 microns (as required in Claims 8-10), or having a water entry pressure in the range of from about 10 psi to about 24 psi (as required in Claim 17). Therefore, Claims 2, 5-7, and 17 distinguish over the applied art for at least these additional reasons, as well.

Claim 18

Claim 18 recites, among other things (emphasis added), “A bifurcated endolumenal prosthesis . . . comprising: a proximal wire support . . . ; a first wire branch section . . . ; a second wire branch section . . . ; and a membrane . . . , the membrane having a membrane proximal end region and membrane distal end regions and configured to inhibit cellular growth through the membrane sufficient to enable the formation of a thin, viable neointimal layer on the lumenal surface of the membrane at least at the membrane proximal and distal end regions.”

In contrast, Shaolian merely explains (emphasis added), “[I]n a central zone 57 of the prosthesis 42, the polymeric sleeve 44 may either be nonporous, or provided with pores of relatively lower porosity.” Nowhere does Shaolian teach or suggest providing a membrane with the neointimal layer-inhibiting characteristics as discussed above.

Because Shaolian fails to teach or suggest at least a prosthesis having a membrane configured to inhibit cellular growth through the membrane sufficient to enable the formation of a thin, viable neointimal layer on the lumenal surface of the membrane at least at the membrane proximal and distal end regions, Shaolian cannot anticipate Claim 18. Therefore, for at least this reason Claim 18 distinguishes over the applied art.

Claim Rejections Under 35 U.S.C. § 103

Claims 31-45 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Shaolian. Applicants respectfully traverse the rejection, as Shaolian fails to teach or suggest, or otherwise render these claims obvious.

Claims 31-33

Claim 31 recites, among other things, “A prosthetic vascular graft, comprising: an expandable tubular wire support; a tubular ePTFE layer . . . having: a wall thickness of less than about 0.15 millimeters; an average density of greater than about 0.75 grams per milliliter; and an average distance between nodes in the range of between about 6 to about 80 microns; so that the ePTFE layer prevents the formation and nourishment of a viable neointimal layer therethrough along portions of the tubular ePTFE layer’s axial length, which are in contact with a vessel wall.”

The Office Action reasons that since Shaolian discloses homogenous or varying porosity characteristics, and provides examples in which the sheath may be nonporous or provided with pores of relatively low porosity in areas where anchoring is less of an issue (which are only areas that are not in contact with a vessel wall), that it would be obvious to configure a sheath to prevent cellular growth through portions of the sheath that contact the vessel wall. Even though the Applicants respectfully disagree, even if true, Shaolian’s limited porosity and wall thickness disclosure would still fail to render Claim 31 obvious.

For example, at col. 6, lines 49-52, Shaolian merely explains, “The porosity characteristics of the polymeric sleeve 44 may be either homogenous throughout the axial length of the prosthesis 42, or may vary according to the axial position along the prosthesis 42” and at lines 65-67, that “in a central zone 57 of the prosthesis 42, the polymeric sleeve 44 may either be nonporous, or provided with pores of relatively lower porosity.” Shaolian is silent as to the other language provided by Claim 31, including a tubular ePTFE layer having an average density of greater than about 0.75 g/ml, an average distance between nodes in the range of between about 6 to about 80 microns, and the fact that the layer prevents formation and nourishment of a viable neointimal layer therethrough specifically along portions of the axial length which are in contact with a vessel wall.

Indeed, at least these particular differences between Shaolian and the claims at issue would not be obvious to one of ordinary skill in the pertinent art. Throughout their specification

the Applicants explain the complex relationship between wall thickness, average density, and intermodal distance, and that “When these characteristics are properly selected, and unlike prior art ePTFE sleeves . . . the polymeric sleeve 44 of the present invention will prohibit the formation of a viable neointimal layer through the wall of the sleeve and along the sleeve’s inner surface 254.” Paragraph [0071].

Therefore, because Shaolian, does not teach or suggest all of the language of Claim 31, even if modified as suggested, Shaolian cannot render Claims 31 obvious. Therefore, for at least these reasons, Claims 31 distinguishes over the applied art.

Furthermore, in responding to the Applicants’ previous arguments that Shaolian actually teaches away from preventing tissue ingrowth through portions of a sheath that contact a vessel wall, the Office Action explains that “disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments.” Office Action, page 4 (citing In re Susi, 440 F.2d 442 (C.C.P.A. 1971)).

However, Shaolian does not provide “broader disclosure or nonpreferred embodiments” as were provided in Susi. Instead, Shaolian clearly explains, “In a preferred embodiment . . . the material of the sleeve 44 is sufficiently porous to permit ingrowth of endothelial cells,” or, porosity can vary along the prosthesis’ axial length, but even when varying, “At least a proximal portion 55 and a distal portion 59 of the prosthesis 42 will seat against the native vessel wall, proximally and distally of the aneurysm [and in] these proximal and distal portions, the prosthesis preferably encourages endothelial growth, or, at least, permits endothelial growth to infiltrate portions of the prosthesis in order to enhance anchoring and minimize leakage.” Shaolian, column 6, lines 41-61. Shaolian, unlike in Susi, fails to provide a broader disclosure or nonpreferred embodiment that teaches, suggests, or otherwise renders the claims obvious.

In Susi, the prior art reference (Knapp) explicitly disclosed a particular compound, which Knapp referred to as a “particularly preferred embodiment,” and which according to the Court, included only one difference “of little importance” from Susi’s claimed compound. Id., at 445; M.P.E.P. § 2144.08(II)(A)((4)(c) (“the difference from the particularly preferred subgenus of the prior art was a hydroxyl group, a difference conceded by applicant ‘to be of little importance’”) (citing In re Susi). However, Susi also disclosed a particular subclass of the “particularly preferred embodiment” compound, which he referred to as his “most particularly preferred

[embodiments].” Susi, at 446. The Court explains that the “most particularly preferred [embodiments]” were “not as close structurally to [Susi’s] additives as are other species within the ‘particularly preferred’ class” Id. Susi argued that Knapp taught away from Susi’s invention because even though Knapp disclosed embodiments very similar to Susi’s claimed invention (the “particularly preferred embodiments”), Knapp also disclosed other, less similar, embodiments, and characterized those less similar embodiments as the “*most* particularly preferred [embodiments]”. Id. (emphasis added). The court rejected this argument, stating, “We cannot accept the suggestion that one is significantly ‘taught away’ from a ‘particularly preferred embodiment’ by the suggestion . . . that something else may be even better.” Id.

Susi’s facts differ significantly from those in the present case, and therefore, the Office Action’s broad application of Susi does not apply. For example, as discussed above, Shaolian, unlike Knapp, fails to provide a broader disclosure or nonpreferred embodiment that teaches, suggests, or otherwise renders obvious, an ePTFE layer that prevents the formation and nourishment of a viable neointimal layer therethrough along portions of the tubular ePTFE layers axial length, which are in contact with a vessel wall (as provided in Claim 31); a polytetrafluoroethylene layer which prevents tissue ingrowth through portions of the layer that contact a vessel wall when the prosthesis is implanted to span an aneurysm (as provided in Claim 32); or inhibiting the formation of a viable neointimal on a second side of a layer throughout a contacting portion, nourished through the layer (as provided in Claim 33).

Indeed, the M.P.E.P. clearly explains that “A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” M.P.E.P. § 2141.02 (emphasis in original). When reading Shaolian as a whole, particularly column 6, lines 41-67, one must conclude that Shaolian’s sleeve teachings all include sufficient porosity to permit tissue ingrowth at least at the proximal and distal, tissue contacting portions.

Shaolian’s teaching regarding the desirability of tissue ingrowth is consistent with ePTFE graft teachings of others, as well. For example, portions of paragraphs [0071]-[0077] of the present application’s publication explain that neointima forming sleeves are well known in the art, and that examples of such sleeves are taught by Goldfarb (U.S. Patent No. 6,436,135). Goldfarb himself explains:

Extensive efforts have been made toward the fabrication of
a porous vascular structure which would permit uniform

transmural tissue ingrowth sufficient to assure the formation and continuous nutrition of a true neointimal layer.

Goldfarb, column 2, lines 56-59. In view of the desirability of such tissue ingrowth, Goldfarb further explains:

Accordingly, it is a major objective of the present invention to provide a homogeneously porous vascular prosthesis characterized by small nodes interconnected by extremely fine fibrils to form an open superstructure which will allow uniform, controlled transmural cellular ingrowth and thereby assure the establishment and maintenance of a thin, viable neointima as well as firm structural integration of the graft into the body.

Goldfarb, column 3, lines 27-34. Goldfarb explains that ingrowth not only promotes and nourishes a neointima, but also helps to firmly attach such structures to the vasculature. For example, in Claim 1, Goldfarb claims:

A prosthetic vascular structure of expanded polytetrafluorethylene . . . whereby said structure may provide for the smooth flow of blood between at least two points in a living organism while controlling cellular ingrowth through the wall of the tubular configuration to promote and nourish a thin, viable neointima over the inner surface thereof and to firmly attach said prosthetic vascular structure to adjacent tissue of said living organism.

Under the established belief that providing tissue ingrowth is desirable when providing ePTFE structures as vascular grafts, Shaolian explains that when providing such structures to span across an aneurysm, tissue ingrowth at the region spanning across the aneurysm, which would not contact with the vasculature at the aneurismal sac, is not helpful. For example, Shaolian explains, "A central portion 57 of the prosthesis spans the aneurysm, and anchoring is less of an issue." Shaolian, column 6, lines 61-63. Therefore, in this region, Shaolian's prosthesis need not have sufficient porosity to encourage endothelial growth.

However, Shaolian clarifies that at the proximal and distal portions of the prosthesis (the portions of the prosthesis that contact the vasculature), "the prosthesis preferably encourages endothelial growth, or, at least, permits endothelial growth to infiltrate portions of the prosthesis in order to enhance anchoring and minimize leakage." Shaolian, column 6, lines 57-61.

Since Shaolian, as well as other art, all teach the desirability of tissue ingrowth through an ePTFE structure in contact with vascular structure, such as at a sheath's proximal and distal end

regions, it would be improper to modify such teachings to be inconsistent with, or unsatisfactory for, such intended purposes. Shaolian itself fails to describe any embodiments where tissue ingrowth is not provided at proximal and distal end regions.

Indeed, Shaolian not only teaches away from the Office Action's proposed modification, as discussed above, but the proposed modification would impermissibly render Shaolian unsatisfactory for its intended purpose. See M.P.E.P. § 2143.01(V) ("a proposed modification cannot render the prior art unsatisfactory for its intended purpose"). Therefore, for at least this reason as well, Shaolian cannot render Claims 31-33 obvious.

Claim 31 further distinguishes over Shaolian for the additional features required by that claim. For example, nothing in Shaolian teaches or suggests an ePTFE layer having the claimed characteristics, such as a wall thickness of less than about 0.15 mm; an average density of greater than about 0.75 g/ml; and an average distance between nodes in the range of between about 6 to about 80 microns. Claim 31 therefore distinguishes over the applied art for at least these reasons, as well.

Claim 32 further distinguishes over Shaolian for the additional features required by that claim. For example, nothing in Shaolian teaches or suggests an ePTFE layer in which either the density is greater than about 1g/ml or the wall thickness is less than about 0.2 mm, or both. Claim 32 therefore distinguishes over the applied art for at least these reasons, as well.

Claim 33 further distinguishes over Shaolian for the additional features required by that claim. For example, nothing in Shaolian teaches or suggests providing an ePTFE layer with a density of greater than about 0.75 g/ml and a wall thickness of less than 0.2 mm. Claim 33 therefore distinguishes over the applied art for at least these reasons, as well.

Because Shaolian, does not teach or suggest all of the language of Claims 31-33, even if modified as suggested, Shaolian cannot render Claims 31-33 obvious. Therefore, for at least these reasons as well, Claims 31-33 distinguish over the applied art.

Claims 34-45

Claim 34 recites, among other things, "An endolumenal prosthesis . . . comprising: a tubular wire support . . . and a tubular ePTFE sheath on the wire support, the tubular sheath having a proximal end and a distal end and being configured to have a water entry pressure of at

least about 10 psi, and wherein the tubular sheath is configured to inhibit the formation of a viable neointimal layer on the lumenal surface of the sheath through the wall of the sheath.”

Nothing in Shaolian teaches or suggests at least a sheath configured to have a water entry pressure of at least about 10 psi and to inhibit the formation of a viable neointimal layer on the lumenal surface through the wall of the sheath.

Because Shaolian, does not teach or suggest all of the claim language, even if modified as suggested, Shaolian cannot render Claim 34 obvious. Therefore, for at least these reasons, Claim 34 distinguishes over the applied art. Claims 35-45 depend from Claim 34, and therefore distinguish over the applied art for at least the same reasons. In addition, Claims 35-45 distinguish over the applied art for the unique combinations of features recited in those claims.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that this application is in condition for allowance and such action is respectfully requested. If any issues remain or require further clarification the Examiner is respectfully requested to call Applicants' counsel at the number indicated below in order to resolve such issues promptly.


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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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